JUN 0 6 2014

510(k) Summary for BioMonitor Implantable Cardiac Monitor

Date Prepared	June 5, 2014
Sponsor	BIOTRONIK, Inc. 6024 Jean Road Lake Oswego, OR 97035 Establishment Registration 1028232
Manufacturer	BIOTRONIK SE & Co. KG Woermannkehre 1, 12359 Berlin, Germany 011-49-30-689-05-1210 Establishment Registration 9610139
Contact Person	Jon Brumbaugh VP, Regulatory Affairs and Compliance Phone (888) 345-0374 Fax (800) 913-6993 jon.brumbaugh@biotronik.com

Device Information	Trade Name	BioMonitor
	Common Name	Implantable Cardiac Monitor
	Classification Name	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
	Classification	Class II (21 CFR 870.1025)
	Product Code	MXD

General Description:

The BioMonitor is a small, leadless, implantable device that uses three electrodes on the body of the device to continuously monitor the patient's subcutaneous ECG. The BioMonitor is designed to automatically record the occurrence of arrhythmias in a patient. Arrhythmia may be classified as bradyarrhythmia, asystole, or high ventricular rate. The device memory can store up to 13.3 minutes of ECG recordings from automatically detected arrhythmias and up to 22.5 minutes of ECG recordings from patient-triggered episodes. When a patient experiences symptoms, the ECG recordings can be manually triggered by placing a magnet over the BioMonitor.

Predicate Devices:

- Medtronic Reveal XT Model 9529 (K071641, cleared November 21, 2007)
- St. Jude Medical Confirm DM 2100 (K081365, cleared August 15, 2008)

Indication for Use:

The BioMonitor is indicated for:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia

Technological Characteristics and Substantial Equivalence:

The substantial equivalence claim between the subject and the predicate device is supported by the information included in the premarket notification. This includes the following information:

- Description of the subject and predicate devices
- Intended use of the subject and predicate devices
- Performance of the subject and predicate devices
- Technological characteristics of the subject and predicate devices
- Validation testing

Table 1: BioMonitor Compared to Predicate Devices

Technical Data	BioMonitor	Reveal XT	Confirm DM 2100
FDA Clearance	**Subject**	**K071641**	**K081365**
Dimensions (mm) Length x Width x Height	53.3 x 42.7 x 7.1	19 x 62 x 8	18.5 x 56.3 x 8
Volume	12.5 cc	9 cc	6.5 cc
Weight	26 g	15 g	12 g
Longevity	48 months	36 months	36 months
Subcutaneous ECG Recording	Yes	Yes	Yes
Pre and Post Event Storage	Yes	Yes	Yes
SEGM Storage	35.8 min 22.5 min for patient triggered events 13.3 min for auto-activated events Longest/oldest/newest	49.5 min 22.5 min for patient triggered events 27 min for auto-activated events 3 most recent episodes	48 min 3 most recent episodes
Patient Activation	7.5 min per event 7 min prior to activation 0.5 min following activation	7.5 min per event 6.5 min prior to activation 1 min for auto-activated events	1- 4 min prior to activation 10-60s post activation
Asystole Brady/rate drop VT-FVT	40 s/episode 30 s prior auto activation 10 s post auto activation	1 min/episode 30 s prior auto activation Last 30 s of episode	10 – 60 s prior activation 10- 60s post activation
AT/AF	N/A	1 min/episode 30 s prior auto activation Last 30 s of episode	10 – 60 s prior activation 10- 60s post activation
Vector Mapping Required	No	Yes	Yes
Sampling Rate	128 Hz	256 Hz	128 Hz
Auto Activation Triggers	Yes	Yes	Yes
Manual (Patient) Activation Trigger	Yes	Yes	Yes
High Rate Trigger	Yes	Yes	Yes
Programmable High Rate Count	Yes	Yes	Yes
Low Rate Trigger	Yes	Yes	Yes

Technical Data	BioMonitor	Reveal XT	Confirm DM 2100
FDA Clearance	Subject	K071641	K081365
Asystole Trigger	Yes	Yes	Yes
Remote Monitoring	Home Monitoring daily transmissions	CareLink	Transtelephonic Monitoring (TTM)
QRS Detection	Combination signal from 3 vectors	One vector detection	One vector detection

Summary of Testing:

The substantial equivalence claim between the subject and the predicate device is supported by the information included in this premarket notification. This includes the following:

- Comparison of attributes and specifications of the subject and predicate devices
- Subject device risk analysis
- Subject device validation testing which includes the following testing:
    - Functional
    - Mechanical
    - Biocompatibility
    - Electrical Safety / EMC
    - Packaging
    - Sterilization and Shelf life
- Analysis of clinical data to support QRS detection

Conclusion:

BIOTRONIK considers the BioMonitor implantable cardiac monitor to be substantially equivalent to legally marketed predicate devices through the data and information presented. No safety or effectiveness issues were identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

June 6, 2014

Biotronik, Inc.
Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, OR 97035 US

Re: K132960
Trade/Device Name: BioMonitor ICM
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MXD
Dated: May 30, 2014
Received: June 2, 2014

Dear Jon Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

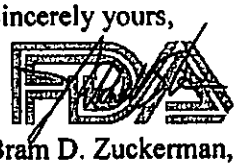
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K132960

Device Name: BioMonitor
Indications for Use:

The BioMonitor is indicated for:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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